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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,913

Applicant(s)

SOLAR ET AL.

Examiner

Melanie Tyson

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-12, 14-17, 19, 20, 22, 23, 25 and 35-57 is/are pending in the application.

4a) Of the above claim(s) 8 and 10 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-3, 5, 6, 8-12, 14-17, 19, 20, 22, 23, 25 and 35-57 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 May 2008 has been entered. Claims 4, 7, 13, 18, 21, 24, and 26-34 are cancelled. Claims 8 and 10 remain withdrawn from consideration.

Claim Objections

2. Claims 11, 12, 14, 39, and 49 are objected to because of the following informalities: they all recite the limitation "standoff features" when line 14 of claim 11 defines the limitation as "standoff members." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 36, 41, 49, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "the bone screw" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 36, claim 1 recites the limitation a deformable "spherical socket." Claim 36 then recites the limitation "wherein the spherical socket defines less than an entire sphere." It is unclear as to how a spherical socket can be further defined as less than an entire sphere. For examination purpose the limitation has been interpreted as a sphere containing discontinuities due to the relief openings that define a complete passage between at least two members of the spherical socket.

Claim 41 depends from claim 18, which has been cancelled. Therefore, claim 41 is being interpreted as depending from claim 17. Claim 41 recites the limitation "the elastomer band." There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 49, it is unclear as to how a portion of the substantially planar portion extends into the bore at the first standoff feature end since claim 11, from which claim 49 depends, recites that the standoff features "extend from a second side of the substantially planar portion." For examination purposes, the limitation is interpreted as a retention force feature extending into the bore defined by the substantially planar portion as shown in Figure 3B.

Regarding claim 57, it is unclear as to what is meant by the limitation "the passage into the passage." For examination purposes the limitation has been interpreted as the passage that extends into the standoff feature.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, 41, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ray (3,457,922). Ray discloses an alignment device (see entire document) comprising a longitudinal guide portion (longitudinal guide bolt 20), a spherical portion (18), a base unit (16) operable to be positioned relative to a work surface (for example, see Figure 10) having a deformable socket (portion between 16' and 16"), an actuating device (19) operatively connected to the socket without being in direct contact with the spherical socket (for example, see Figure 1), at least one standoff feature (round protruding portions of 11) having a thickness (from left side to right side), wherein the standoff features include a shelf (26) that extends into the bore defined by the standoff feature (portion 26 is considered a "shelf" in that it has a top surface in which the screws are tightened against; for example, see Figure 3) to determine an attachment thickness (diameter of the passage within the shelf which is less than the thickness of the standoff feature since it fits through it), a passage through which an attaching device (27) passes substantially freely (27 can be inserted and removed within the portion of the passage that lies within 26), and a retention force providing member (ball 24) operable to retain the attaching device near the passage (in that the ball 26 presses the outer surface of the shelf portion). Regarding claim 19, the retention force providing member protrudes into a portion of the passage defined by the standoff feature (protrudes into passage within 24). Regarding claim 41, the base defines many grooves that are capable of holding an elastomer band near the passage (for example, see Figure 1). Regarding claim 50, the shelf defines a surface intermediate the first

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standoff feature end and the second standoff feature end in that it extends the entire length of the standoff feature.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3, 5, 9, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. (2003/0114752 A1) in view of Ghajar et al. (4,998,938).

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), and a base unit including a deformable spherical socket portion (1040) in that it compresses when a threaded actuating device (locking ring 432) having engaging threads is screwed over it to engage threads disposed on an outer perimeter of the spherical socket (thus is not in

direct contact with the socket), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a substantially planar portion (140) in which the deformable spherical socket extends from a first side (the top side). Henderson fails to disclose a number of standoff features attached to the base unit extending from a second side (the bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull.

Ghajar discloses an alignment device (see entire document) comprising a longitudinal guide portion (12) and a base unit having a substantially planar portion (22). Ghajar teaches a number of standoff features (20) adapted to contact the work surface along a circle extending from a second side (the bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull (for example, see Figure 5). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Henderson's device with a number of standoff features as taught by Ghajar. Doing so would minimize contact between the device and the patient's skull, thus reducing the risk of infection (for example, see column 2, lines 44-48).

8. Claims 2, 6, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Ghajar et al. as applied to claim 1 above, and further in view of Mowlai-Ashtiani (6,110,182).

Henderson in view of Ghajar discloses the claimed invention except for relief openings in the spherical socket. Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches three relief openings in the spherical socket, one of which forms a complete passage between two sides of the socket, thus forming a discontinuity in the sphere (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson in view of Ghajar having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44).

Regarding claim 38, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the relief openings such that they define a complete passage between at least two members defining at least a portion of the spherical socket of the base, since it has been held that constructing a formerly integral structure (spherical socket) in various elements (two separate members spaced apart by two complete passages) involves only routine skill in the art.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray. Ray discloses the claimed invention except for a retention force providing member located external to, and above the passage. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to provide the retaining force applying member external to, and above the passage since the applicant has not disclosed that such a retaining member provides an advantage, is used for a particular purpose, or solves a stated problem. It appears the prior art force applying retention member would perform equally well as a retention force providing member located external to, and above the passage, especially since the applicant indicates in the disclosure that other well known retention devices would perform equally well (for example, see Figures 1A, 3B, and 3C).

10. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Ghajar et al. as applied to claim 1 above, and further in view of D'Urso (5,752,962).

Henderson in view of Ghajar discloses the claimed invention except for a shelf to determine an attachment thickness in combination with a bone screw, wherein the attachment thickness is less than a standoff feature thickness. D'Urso discloses an alignment device (see entire document) comprising a spherical socket (25) and standoff features (21). D'Urso teaches the standoff features include a shelf (22) for a bone screw (for example, see Figure 4), wherein the attachment thickness (from top to bottom of 22) is less than the standoff feature thickness (from top to bottom of 21). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff features of Henderson in view of Ghajar with a shelf and

bone screw as taught by D'Urso. Doing so would ensure a symmetrical attachment between the device and the skull of a patient, thus reducing the risk of inadvertent movement, such as tilting, of the alignment device during the procedure.

11. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Ghajar et al. as applied to claim 1 above, and further in view of Ray.

Henderson in view of Ghajar discloses the claimed invention except for a shelf that extends into a bore defined by the standoff features. Ray discloses an alignment device comprising a base unit (16) and standoff features (round protruding portions of 11). Ray teaches a shelf (26) that extends into a bore defined by each of the standoff features, wherein the shelf defines a surface intermediate the first standoff feature end and the second standoff feature end in that it extends the entire length of the standoff feature. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff features of Henderson in view of Ghajar with a shelf portion as taught by Ray. Doing so would provide a passage having a surface for holding a bone screw, thus enabling a user to further secure the device to the skull of a patient.

12. Claims 11, 12, 14-16, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and Ghajar et al.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), and a base unit including a deformable spherical socket portion (1040) in that it compresses when a threaded actuating device (locking ring 432) having engaging threads is screwed over it to engage threads disposed on an outer perimeter of the spherical socket (thus is not in direct contact with the socket), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a substantially planar portion (140) in which the deformable spherical socket extends from a first side (the top side). Henderson fails to disclose at least one relief opening, a number of securing devices, and a number of standoff members attached to the base unit extending from a second side (the bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches three substantially equally spaced relief openings in the spherical socket, one of which defines a complete disassociation between two sides of the spherical socket (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after

repeated use (for example, see column 3, lines 40-44). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the relief openings such that they define a complete disassociation between at least two portions of the spherical socket, since it has been held that constructing a formerly integral structure (spherical socket) in various elements (at least two separate members spaced apart by at least two relief openings) involves only routine skill in the art.

Ghajar discloses an alignment device (see entire document) comprising a longitudinal guide portion (12) and a base unit having a substantially planar portion (22). Ghajar teaches at least three truncated cone shaped (wider on top and narrower towards the bottom) standoff members (20) having a number of securing devices (free ends 24 in that they contact to stabilize, or secure, the device above the skull) adapted to contact the work surface along a circle extending from a second side (bottom side) of the substantially planar portion to position the substantially planar portion a distance away from the skull (for example, see Figure 5). Regarding claims 30 and 54, the securing devices (24) pass through the standoff members (20) and extend a length of the truncated cone to engage the skull in that they comprise the entire bottom portion of the standoff members. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Henderson's device with a number of standoff members having securing devices as taught by Ghajar. Doing so

would maximize security while minimizing contact between the device and the patient's skull, thus reducing the risk of infection (for example, see column 2, lines 44-48).

13. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and Ghajar et al. as applied to claim 11 above, and further in view of Ray.

Henderson in view of Mowlai-Ashtiani and Ghajar discloses the claimed invention except for a shelf that extends into a bore defined by the standoff features. Ray discloses an alignment device comprising a base unit (16) and standoff features (round protruding portions of 11). Ray teaches a shelf (26) that extends into a bore defined by each of the standoff features, wherein the shelf defines a surface intermediate the first standoff feature end and the second standoff feature end in that it extends the entire length of the standoff feature, and a retention force applying member (24) extending into the bore of the standoff feature. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff members of Henderson in view of Mowlai-Ashtiani and Ghajar with a shelf portion and retention member as taught by Ray. Doing so would provide a passage having a surface and a retention member for holding a bone screw therethrough, thus enabling a user to further secure the device to the skull of a patient.

14. Claims 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani and Hennig (Patent No. 6,328,748).

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (for example, see Figure 4; element 27), a spherical portion (26), a base unit (20), a spherical socket (25), an actuating device (threaded screw 30 comprises a "threaded ring"), three standoff features (21/22; for example, see Figure 4) capable of contacting the work surface (24) along a circle, a shelf within a perimeter of the standoff features (top surface of 22), wherein the attachment thickness (from top to bottom of 22) is less than the standoff feature thickness (from top to bottom of 21 + 22), a number of securing devices (bone screws in apertures 23), and screw retention features (internal threading of apertures 23). D'Urso fails to disclose that the spherical socket includes relief openings and an insert located within the longitudinal opening.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), a deformable socket (10), and an actuating device (52). Mowlai-Ashtiani teaches the spherical socket (12) contains three relief openings (22; for example, see Figure 2) and the actuating device (52) provides symmetric tightening of the spherical socket (12) around the spherical portion (column 2, lines 15-18 and 50-54). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of

D'Urso having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44).

Hennig discloses an alignment device (see entire document). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an insert in the device of D'Urso as taught by Hennig. Doing so would size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (for example, see column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe since it is well known in the art to utilize probes in surgery (for example, see Mowlai-Ashtiani column 4, lines 31-34).

15. Claims 22 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson in view of Mowlai-Ashtiani, D'Urso, and Hennig.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), and a base unit including a deformable spherical socket portion (1040) in that it compresses when a threaded

actuating device (locking ring 432) having engaging threads is screwed over it to engage threads disposed on an outer perimeter of the spherical socket (thus is not in direct contact with the socket), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a substantially planar portion (140) in which the deformable spherical socket extends from a first side (the top side). Henderson fails to disclose at least one relief opening in a portion of the spherical socket, a number of standoff features attached to the base unit, and an insert.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches at least one relief opening in the spherical portion (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44).

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (27), a spherical portion (26), and a base unit (20). D'Urso teaches a number of standoff features (21/22) to support the base unit above the working space (for example, see Figure 4) and bone screws (screws in apertures 23), wherein a shelf is defined within a perimeter of the standoff features (top surface of 22)

and the attachment thickness (from top to bottom of 22) is less than the standoff feature thickness (from top to bottom of 21 + 22). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Henderson's device with standoff features, shelf, and bone screws as taught by D'Urso. Doing so would ensure a symmetrical attachment between the device and the skull of a patient, thus reducing the risk of inadvertent movement, such as tilting, of the alignment device during the procedure.

Hennig discloses an alignment device (see entire document). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an insert in Henderson's device as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe since it is well

know in the art to utilize probes in surgery (for example, see Mowlai-Ashtiani column 4, lines 31-34).

16. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson in view of Mowlai-Ashtiani, D'Urso, and Hennig as applied to claim 22 above, and further in view of Ray.

Henderson in view of Mowlai-Ashtiani, D'Urso, and Hennig discloses the claimed invention except for a shelf that extends into a passage defined by the standoff features. Ray discloses an alignment device comprising a base unit (16) and standoff features (round protruding portions of 11). Ray teaches a shelf (26) that extends into a passage defined by each of the standoff features, wherein the shelf defines a surface intermediate the first standoff feature end and the second standoff feature end in that it extends the entire length of the standoff feature, such that a bone screw engages the shelf to attach the base unit to the work surface. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff members of Henderson in view of Mowlai-Ashtiani, D'Urso, and Hennig with a shelf portion as taught by Ray. Doing so would provide a passage having a surface for holding a bone screw, thus enabling a user to further secure the device to the skull of a patient.

17. Claims 43-47, 53, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and Magee.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) including a substantially planar portion (414), wherein a deformable spherical socket portion (1040) extends from a first portion (top side), a number of securing devices (screws in mounting holes 416), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (140) extending from a second side (bottom side) of the substantially planar portion adapted to mount directly to a skull of a subject and having a shelf (422) that extends into the standoff feature (140) in that the top portion of 422 extends into an intermediate portion of 140. Regarding claim 53, the standoff feature extends from the base unit a distance, therefore, a portion of the base unit is a distance away from the work surface. Henderson fails to disclose at least one relief opening in a portion of the spherical socket and a retaining force applying member.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10). Mowlai-Ashtiani teaches three substantially equally spaced relief openings in the spherical socket, one of which defines a complete disassociation between two sides of the spherical socket (for example, see Figure 3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the

spherical socket of Henderson having relief openings as taught by Mowlai-Ashtiani. Doing so would help to maintain the structural integrity of the spherical socket after repeated use (for example, see column 3, lines 40-44). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the relief openings such that they define a complete disassociation between at least two portions of the spherical socket forming at least two fingers that are operable to deform independently of one another, since it has been held that constructing a formerly integral structure (spherical socket) in various elements (at least two separate fingers spaced apart by at least two relief openings) involves only routine skill in the art. Such fingers would inherently deform relative to the first portion.

Magee discloses a bone fixation device holder (see entire document). Magee teaches a retaining force applying member for a bone screw (retaining element 62, Figure 10; column 5, lines 31-34) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Henderson with retention members as taught by Magee. Doing so would further assist in proper placement and securement of the device. Regarding claims 46 and 57, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retaining force applying member in the form of an elastomer band or protruding member as claimed, since the applicant has

not disclosed that an elastomer band or protruding member provide an advantage, are used for a particular purpose, or solve a stated problem. It appears the prior art force applying retention member would perform equally well as an elastomer band or protruding member, especially since the applicant indicates in the disclosure that other well known retention devices would perform equally well (for example, see Figures 1A, 3B, and 3C).

18. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and Magee as applied to claim 43 above, and further in view of Ray.

Henderson in view of Mowlai-Ashtiani and Magee discloses the claimed invention except for a shelf that extends into a passage defined by the standoff features. Ray discloses an alignment device comprising a base unit (16) and standoff features (round protruding portions of 11). Ray teaches a shelf (26) that extends into a passage defined by each of the standoff features, wherein the shelf defines a surface intermediate the first standoff feature end and the second standoff feature end in that it extends the entire length of the standoff feature, such that an attaching device engages the shelf to attach the base unit to the work surface. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the standoff members of Henderson in view of Mowlai-Ashtiani and Magee with a shelf portion as taught by Ray. Doing so would provide a passage having a surface for holding a

retention device, thus enabling a user to further secure the device to the skull of a patient.

19. Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of D'Urso and McGee.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), and a base unit including a deformable spherical socket portion (1040) in that it compresses when a threaded actuating device (locking ring 432) having engaging threads is screwed over it to engage threads disposed on an outer perimeter of the spherical socket (thus is not in direct contact with the socket), wherein the actuating device has the ability to cause substantially symmetric tightening of the spherical socket, and a substantially planar portion (140) in which the deformable spherical socket extends from a first side (the top side). Henderson fails to disclose at least one standoff feature having a shelf as claimed and an elastomer band.

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (27), a spherical portion (26), and a base unit (20). D'Urso teaches a number of standoff features (21/22) to support the base unit above the working space (for example, see Figure 4) and bone screws (screws in apertures 23), wherein a shelf is defined within a perimeter of the standoff features (top surface of 22) and the attachment thickness (from top to bottom of 22) is less than the standoff feature thickness (from top to bottom of 21+22). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for

improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Henderson's device with standoff features, a shelf, and bone screws as taught by D'Urso. Doing so would ensure a symmetrical attachment between the device and the skull of a patient, thus reducing the risk of inadvertent movement, such as tilting, of the alignment device during the procedure.

Magee discloses a bone fixation device holder (see entire document). Magee teaches a retaining force applying member for a bone screw (retaining element 62, Figure 10; column 5, lines 31-34) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Henderson with retention members as taught by Magee. Doing so would further assist in proper placement and securement of the device. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retaining force applying member in the form of an elastomer band as claimed, since the applicant has not disclosed that an elastomer band provides an advantage, is used for a particular purpose, or solves a stated problem. It appears the prior art force applying retention member would perform equally well as an elastomer band, especially since the applicant indicates in the disclosure that other well

known retention devices would perform equally well (for example, see Figures 1A, 3B, and 3C).

Response to Arguments

20. The amendment submitted 27 May 2008 overcomes the 112 rejection of claims 11, 12, 14-16, 38-40, and 43-47 of the previous office action. Therefore, the 112 rejection of the previous office action has been withdrawn.

21. Applicant's arguments with respect to claims 1, 11, and 17 have been considered but are moot in view of the new ground(s) of rejection.

22. Applicant's arguments filed 27 May 2008 with respect to claims 22 and 43 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied are not properly combined and fail to teach each and every element claimed. Examiner respectfully disagrees.

Regarding claim 22, the applicant argues that the combination of Hennig, D'Urso, and Mowlai-Ashtiani appears to be improper, since Mowlai-Ashtiani and D'Urso are directed to sockets that are positioned relative to a skull, but not driven into the skull, wherein the socket of Hennig is driven into the skull. It is the examiner's position that the Hennig reference was used simply to provide the teaching that inserts are well known in the art and inserts may be used with either socket embodiment. The position of D'Urso's socket is not being modified by Hennig. Therefore, combination is proper. Applicant further argues that D'Urso fails to disclose a shelf defined "within a perimeter of the standoff features." It is the examiner's position that the standoff features include elements 21 and 22, in which the shelf portion includes the top portion of element 22.

The top portion of element 22 is within the perimeter of elements 21 and 22, therefore, D'Urso discloses a shelf portion as claimed.

Regarding claim 43, the applicant argues that the combination of Henderson and Mowlai-Ashtiani is improper, since Henderson's actuating device would be unable to screw down over Mowlai-Ashtiani's actuating device 50. However, it is the examiner's position that Henderson's actuating device is not being modified with Mowlai-Ashtiani's actuating device. The Mowlai-Ashtiani reference is used simply to provide the teaching that relief openings as claimed are well known in the art for use in deformable spherical sockets and the relief openings may be used with either type of actuating device embodiment. Applicant further argues if complete separations were present in Mowlai-Ashtiani's spherical portion, the member portions would simply fall apart. However, it is the examiner's position that Henderson's spherical portion is being modified, not Mowlai-Ashtiani's and Henderson's substantially planar base portion would hold the separated members together. Therefore, combination is proper.

Regarding the applicant's arguments with respect to dependent claim 46, it is the examiner's position that such a modification would have been obvious to one having ordinary skill in the art at the time the invention was made (see new rejection above for details). Regarding the applicant's arguments with respect to dependent claim 47, it is the examiner's position that the prior art discloses a shelf as claimed (see new rejection above for details).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
July 28, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773